

**REMARKS**

**I. Disposition of the Claims**

Claims 41-46, 49-51, 53-55, 57, and 58 are currently pending in the application.

As discussed below, claim 41 was amended to replace the variable "P" in formula (b) with the variable "M," as well as amending the text of the claim in a corresponding manner. Additionally, the specification was amended in five instances to make a similar replacement.

The foregoing amendments are identical to the amendments originally filed June 15, 2004, but not considered by the Examiner prior to the issuance of the outstanding Office Action. A copy of the Auto-Reply Facsimile Transmission indicating that the previous Amendment, which totaled 64 pages, was filed via facsimile on June 15, 2004, is attached.

Applicants resubmit these amendments in the present response in the event that the Amendment filed June 15, 2004, was not properly matched with the present application, and subsequently considered by the Examiner. Since the Examiner did not issue a Supplemental Action, as specified by M.P.E.P. § 714.15, to address Applicants' amendments and arguments contained in the Amendment filed June 15, 2004, it is presumed that this originally-filed Amendment was never properly matched with the present application.

Applicants submit that no new matter was introduced by these amendments, which are merely clerical in nature, and which were undertaken solely at the request of Examiner Mark Shibuya and Supervisory Patent Examiner Andrew Wang. Therefore, this Amendment should allow for immediate action by the Office.

## II. Interview

Although it was not addressed in the Office Action dated June 25, 2005, a personal interview was conducted with Examiner Shibuya and Supervisory Patent Examiner Wang on May 18, 2004. Applicants again wish to thank Examiners Shibuya and Wang for granting Applicants' representative, Mark Sweet, the courtesy of this personal interview conducted on May 18, 2004.<sup>1</sup> During this interview, Applicants' representative and the Examiners discussed the Applicants' use of variable "P" in figure (b) in claim 41. The Examiner's pointed out that the use of the variable "P" could cause confusion since the chemical symbol "P" represents phosphorus. In an attempt to avoid any possible confusion that this chemical symbol may cause, Applicants' representative agreed to amend claim 41, as well as all similar occurrences in the specification, to replace the variable "P" with another variable that does not represent a chemical element.

Applicants' representative and the Examiners additionally discussed the rejection under 35 U.S.C. § 112, first paragraph. In particular, the Applicants' representative and the Examiners discussed the requirements of 35 U.S.C. § 112, first paragraph, Applicants' previous Response addressing the *Wands* factors, and the guidance provided by the instant specification. U.S. Pat. No. 5,693,791 to Truett ("Truett"), which was previously relied upon by the Examiner in a rejection under 35 U.S.C. § 103(a) that has since been withdrawn, was also discussed as generally teaching that antibiotic moieties linked together can exhibit antibiotic properties.

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<sup>1</sup> The substance of this interview was first discussed in the Amendment filed June 15, 2004. In order to ensure that the substance of this interview is made of record, Applicants again include a discussion of this interview.

**III. Rejection Under 35 U.S.C. § 112**

The Examiner rejected claims 41-46, 49-51, 53-55, 57, and 58 under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in a way as to enable one of ordinary skill in the art to use the invention. Final Office Action, p. 2. In response to Applicants' arguments submitted April 12, 2004, the Examiner stated that these arguments were not persuasive because "the cited prior art publications indicate that the art is unpredictable, and the specification's disclosure does not overcome the unpredictability in the art." *Id.* at p. 3. Applicants respectfully disagree.

The Examiner's position in the outstanding Office Action appears to predominantly focus on only one of the many factors, namely the level of unpredictability in the art, that needs to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement, and whether any experimentation necessary is "undue." In addition to the level of unpredictability in the art emphasized by the Examiner, these many factors, known as the *Wands* factors, also include: (1) the breadth of the claims; (2) the nature of the invention; (3) the state of the prior art; (4) the level of ordinary skill; (5) the amount of direction provided by the inventor; (6) the existence of working examples; and (7) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. M.P.E.P. §2164.01(a), citing *In re Wands*, 858 F.2d 731, 737 (Fed. Cir 1988)). In evaluating these *Wands* factors, the Examiner's analysis must consider all the evidence related to each one of these factors, and any conclusion of nonenablement must be based on the evidence as a whole.

Turning to the level of unpredictability in the art, Applicants respectfully reiterate, as first discussed during the personal interview on May 18, 2004, that at the time Applicants filed the present specification, it was known in the art that two antibiotic moieties linked together can exhibit antibiotic properties. In support of this position, Applicants again direct the Examiner's attention to Truett, which issued as a United States patent on December 2, 1997. Truett discloses "a wide variety of antibiotics of new and novel structure and antimicrobial activity." Truett at col. 1, lines 5-7. Truett, which does not teach or suggest the compounds recited in Applicants' pending claims, contains the general teaching that "the linking of two antibiotic moieties functioning in different fashions . . . can be of value [as antibiotics]." Truett at col. 1, lines 24-27. Truett further teaches that the linking of two antibiotic moieties via a linking group can produce structures "with a wide range of antibiotic activity." *Id.* at col. 1, lines 45-50.

Accordingly, one of ordinary skill in the art would have reason to believe at the time the present specification was filed that two antibiotic moieties linked together can have antibacterial activity. This is in direct contrast to the Examiner's statements regarding unpredictability set forth on pages 3 and 5 of the final Office Action. Truett therefore provides evidence challenging the Examiner's position regarding the level of unpredictability in the art.

The Examiner turns to the various portions of the specification that were highlighted in Applicants' Response filed April 12, 2004, to show that a sufficient amount of guidance was in fact provided by the present specification to use the claimed compounds. Specifically, the Examiner states that the disclosure of standardized testing and biological testing of the compounds "are prophetic and not working

examples. Thus nowhere does the specification actually show antibacterial activity using the claimed invention.” Final Office Action at p. 4. Moreover, the Examiner states “Applicant’s [sic] argument seeks to bootstrap the specification into a disclosure that overcomes the art recognized unpredictability of antibacterial activity using the claimed invention . . . without an actual teaching, anywhere in the specification, of such antibacterial activity.” *Id.* at p. 5. Applicants submit that the Examiner’s position is legally incorrect.

As emphasized in the response filed April 12, 2004, Applicants submit the enablement requirement of 35 U.S.C. § 112, first paragraph, does not require working examples. *Atlas Powder Co. v. E.I. Du Pont De Nemours & Co.*, 750 F.2d 1569 (Fed. Cir. 1984); *In re Long*, 368 F.2d 892, 895 (C.C.P.A. 1966) (stating that “[t]he absence of a working example, denominated as such, does not compel the conclusion that a specification does not satisfy the requirements of 35 U.S.C. 112”); and M.P.E.P. § 2164.02 (“[c]ompliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed. An example may be ‘working’ or ‘prophetic.’”). Interestingly, this case law was not addressed by the Examiner in the final Office Action.

The legal precedent established by the Federal Circuit, and its predecessor the Court of Customs and Patent Appeals, as well as the direction provided by the Manual of Patent Examining Procedure, make abundantly clear that the Examiner can not simply dismiss the guidance provided by examples, merely because the examples are prophetic. Such guidance provided by the present specification includes, for example, the well-known antibacterial activity testing described in “Antibiotics in Laboratory

Medicine,” which was incorporated by reference (Specification at p. 112), and the Biological Examples, which provide further details for determining the antibacterial activity of the compounds according to the present invention (Specification at pp. 132-134). In contrast to dismissing the prophetic examples, the Examiner must instead consider the guidance regarding how to use the claimed invention provided by these prophetic examples. This the Examiner has not done.

The Examiner next states that “[s]upport for the conclusion that the antibacterial testing is ‘non-routine’ has been shown by the cited publication of the Physicians Desk Reference 53<sup>rd</sup> Edition.” Applicants submit that this “conclusion” ignores the guidance provided by the present specification; namely the facts that the present specification (1) contains the express statement that processes for testing the antibacterial activity were well known in the art, (2) incorporates by reference “Antibiotics in Laboratory Medicine,” which describes the well-known testing, and (3) sets forth Biological Examples, which describe the testing.

Moreover, with respect to the Examiner’s reliance on the Physicians Desk Reference, Applicants again reiterate that this document shows the state of the art at a time before Applicants’ invention. In contrast, the present specification describes Applicants’ invention, which was an improvement on the state of the art. In other words, in describing their technological advancement over the prior art, Applicants provided a specification setting forth how to make and use the claimed invention, i.e., an enabling disclosure.

For at least these reasons, Applicants respectfully submit that the present specification enables one of ordinary skill in the art to use the invention without undue

experimentation. Withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, is therefore requested.

**IV. Conclusion**

Applicants respectfully request reconsideration of the application, and the timely allowance of all pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: September 22, 2004

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